In re Appln. of Jobst LAHRSOW Appln. No. 10/576,151

Reply to Final Action of March 26, 2010 Amend. After Final dated May 12, 2010

REMARKS

The Final Office Action of March 26, 2010, and the prior art relied upon therein, including the newly cited prior art, have been carefully studied. The amendment above incorporates the dependent part of claim 24 into claim 11 and the dependent part of claim 34 into claim 26 so that the claims in the application for consideration are claims 11, 13-20, 25, 26-33 and 35; these claims define patentable subject matter warranting their allowance. Favorable reconsideration, entry of the amendments presented above, and allowance are earnestly solicited.

As indicated above, main claim 11 is amended above to make it correspond with claim 24 rewritten in independent form, and main claim 26 is amended above to make it correspond with claim 34 rewritten in independent form. As claims 24 and 34 were already pending, no new issues are introduced by the amendments presented above, so the amendments presented above should be entered even if only for purposes of appeal. However, Applicants believe that no appeal should be necessary because the claims define patentable subject matter under the provisions of all of the applicable statues, including §§102, 103 and 112.

Claims 11, 13-17, 19, 20, 24-30 and 32-35 have been rejected as obvious under \$103 from newly cited and applied Maeda et al USP 4,889,728 (Maeda) in view of newly cited and applied Lederman U.S. Application Publication 2003/0068408 (Lederman). This rejection is respectfully traversed.

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Maeda discloses a chewing gum kit including a liquid component (B) and a special powdery chewing gum component (A) that can be turned into a chewable mass by mixing with the liquid (B). The special powdery component contains hydrous crystalline maltose formed by hydrating anhydrous crystalline maltose (Abstract). In more detail, the powdery chewing gum component (A) can be obtained by mixing and kneading a gum base, a humectant, and anhydrous crystalline maltose (column 2, lines 37-41). As revealed in Figs. 5 and 6, the special effect of this mixture is that the anhydrous crystalline maltose absorbs moisture and turns into hydrous crystalline maltose, whereby a hydrated chewing gum is obtained (see column 2, lines 49-54). As a result of such hydration, the hydrous crystalline maltose has an increased volume (see column 2, line 60 to column 3, line 3, and Fig. 6).

The hydrated chewing gum has a whitish appearance (see column 2, lines 55-57). This whitish appearance results from the hydrous crystalline maltose. The hydrous crystalline maltose scatters light inhomogenously, rendering opaque even thin layers of the hydrated chewing gum. The term "whitish" does not relate to transparency, but to white color (see column 5, line 29). Of course, the white color of the chewing gum can be changed to other colors such as red (see column 5, table 1), but the chewing gum will always stay opaque due to light scattering and will never be transparent.

The PTO recognizes that Maeda by itself does not anticipate or make obvious any of Applicant's claims. In paragraph 6 on page 3 of the Final Action, the PTO states that "Maeda does not disclose adding a reactive source of calcium to In re Appln. of Jobst LAHRSOW Appln. No. 10/576,151 Reply to Final Action of March 26, 2010

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the aqueous solution and adding phosphorous acid to the solution." According to the rejection (as best understood), the PTO position is that the person of ordinary skill in the art would have learned from Lederman that Maeda should be modified in such a way as to reach Applicant's invention. In this regard, the final rejection states in paragraph 9 that it "would have been obvious... to substitute the water in the method of making gum disclosed by Maeda with the reconstituted powder in

First in this regard, because the Maeda hydrated chewing gum is opaque, there is nothing in Lederman which could possibly change the Maeda opaque chewable mass to a transparent mass, without destroying Maeda for its intended function of providing increased volume as a result of hydration.

water disclosed by Lederman." Applicant respectfully disagrees.

Lederman discloses a method of making powdered mineral salts comprising calcium (see paragraph [0021]). These resulting powdered salts are highly soluble and clear when reconstituted in water or other aqueous solutions (see paragraphs [0017] and [0021] of Lederman). Although the powdered calcium salts, when reconstituted in water, are clear, these reconstituted calcium salts will not and cannot lead to a transparent and homogenous chewable mass when added to the mixture disclosed by Maeda.

Furthermore, it is pointed out that the preferred calcium content of 1000 mg/8 oz (= 4.41 g/kg) disclosed by Lederman relates to the aqueous solution. Adding this aqueous solution to gelatin would lead to a completely different calcium content. Hence, Lederman can give a person skilled in the art no hint on what calcium content is effective for both (1) remineralizing tooth enamel and (2) which does not affect the

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homogeneity and transparency of the resulting chewable mass. The same applies for the phosphoric acid content.

Furthermore, according to Lederman the used acid, e.g. the phosphoric acid, combines with the calcium to form a salt (see paragraph [0024] of Lederman). However, according to the present invention, free phosphoric acid is added that remains free and does not combine with the calcium to a salt. It is pointed out that the term "phosphoric acid content" relates to the final product, namely the chewable mass and not to an intermediate product as the aqueous solution disclosed by Lederman. Due to the free phosphoric acid, the remineralization effect is enhanced according to the present invention.

Accordingly, even if it were obvious to combine the references, respectfully denied by Applicant for the reasons pointed out above, the resultant reconstructed Maeda (Maeda modified by Lederman as proposed in the rejection) would not correspond to the claimed invention. In addition, Applicant does not see that the prior art provides any reasonable expectation of the enhanced effects achieved by the present invention.

The Applicant surprisingly found that a chewable mass on the basis of gelatin produced by the claimed method is homogenous and transparent, and also has a good remineralization effect. Due to the comparatively low calcium content, calcium cannot lead to turbidity of the gelatin such that Applicant's chewable mass is homogenous and transparent (see paragraph [0012], [0013] and [0020] of Applicant's published U.S. application 2007/0116799).

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The Applicant found out that despite this comparatively low calcium content, the chewable mass of the present invention has a good remineralization effect. This effect is surprisingly achieved due to the fact that the local concentration is particularly high due to the chewable mass adhering on the tooth surface and saliva-conditioned removal of calcium and phosphate ions does not take place to a significant degree in the contact area between the chewable mass and the tooth (see paragraph [0023] of Applicant's published U.S. application). Due to the phosphoric acid content of between 15 and 500 mMol/kg, a strongly acidic environment is provided during the remineralization of tooth enamel such that the remineralization effect is enhanced. A higher calcium content would adversely affect the homogeneity and transparency of the gelatin. A lower calcium content would adversely affect the remineralization effect

Neither Maeda nor Lederman can give a person skilled in the art any hint on how to produce a chewable mass on the basis of gelatin which is homogenous and transparent, and which also has a good remineralization effect. Considering the two references together does not lead to the present invention. Attempting to modify Maeda in any way which would eliminate hydration of the hydrous crystalline maltose thereby inevitably providing a opaque material cannot have been obvious.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 18 and 31 have been rejected as obvious under $_{
m 35}$ USC $_{
m S103}$ from Maeda in view of Lederman as applied against

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the main claims as discussed above, and further in view of Yang et al U.S. Application Publication 2001/0051197 (Yang). This rejection is respectfully traversed.

Yang does not make up for the aforementioned deficiencies of the proposed combination of Maeda in view of Lederman, and indeed has not been cited for that purpose. As claims 18 and 31 ultimately depend from claims 11 and 26 respectively, they respectively incorporate the subject matter of claims 11 and 26. Regardless of what Yang teaches or suggests with respect to the dependent portions of claims 18 and 31, Yang cannot cure the deficiencies of the combination of Maeda in view of Lederman for the reasons pointed out above.

Yang discloses that the water solubility of calcium is enhanced (better) when at least two different organic acids are combined with a basic calcium salt (see paragraph [0162]). However, a better water solubility of the calcium simply means that more calcium is dissolved in water, and this would affect the thickening reaction of the gelatin in a negative way such that the resulting chewable mass would be turbid and lumpy and not transparent and homogenous (see paragraph [0012] of Applicant's published U.S. application).

According to the present invention, it is important that the calcium content is kept between 50 and 150 mMol/kg in the finished product, namely the chewable mass. Starting from this calcium content, the transparency and homogeneity of the chewable mass and its remineralizing capacity can be controlled by using differing calcium-complexing acids (see paragraph [0028] of Applicant's published U.S. application).

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Neither Lederman nor Yang give a person skilled in the art any hint on how to control the transparency and homogeneity and simultaneously the remineralizing capacity of a gelatin based chewable mass. It is pointed out that for dissolving a certain amount of calcium salts in water, it is not compulsory to use differing calcium-complexing acids. However, Applicant surprisingly found out that differing calcium-complexing acids not only improve the solubility but also the remineralizing effectiveness due to the level of acidity (see paragraph [0029] of Applicant's published U.S. application).

Again, just like the consideration of Maeda and Lederman does not lead the person of ordinary skill in the art to subject matter of Applicant's main claims, the consideration of Maeda, Lederman and Yang do not lead the person of ordinary skill in the art to the subject matter of claims 18 and 31. Withdrawal of the rejection is in order and is respectfully requested.

In the section on page 6 of the Office Action under the heading "Response to Arguments", particularly in paragraph 21, the PTO says in effect that the inherent effect of transparency and homogeneity may be ignored because these features are not expressed in the main claims. Applicant respectfully disagrees. Nevertheless, the provision of transparency and homogeneity, always present in claims 24 and 34, are inserted into the main claims and thus all of Applicant's claims. Paragraph 21 does not make clear its relevance to original claims 24 and 34.

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The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of Applicant's claims.

Applicant believes that all issues raised in the Final Rejection have been addressed above in a manner that should lead to patentability of the present application. Favorable consideration, entry of the amendments above, and early formal allowance are respectfully requested.

If the Examiner has any questions or suggestions, she is respectfully requested to contact the undersigned at (202) 628-5197.

Respectfully submitted, BROWDY AND NEIMARK, P.L.L.C. Attorneys for Applicant

By

Sheridan Neimark

Registration No. 20,520

SN:ltm 0.18M1%rsu\lahrsov4\Pto\2010-05-14 Reply.doc Telephone No.: (202) 628-5197 Facsimile No.: (202) 737-3528